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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier D. Hawkins

Food and Drug Administration

[Docket No. 03D–0111]

Draft Guidance for Federal Agencies and State and Local Governments; Potassium Iodide Shelf Life Extension; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for Federal agencies and State and local governments entitled "Potassium Iodide Shelf Life Extension." This document is intended to provide guidance to Federal agencies and to State and local governments on testing to extend the shelf life of stockpiled potassium iodide (KI) tablets. The draft guidance discusses FDA recommendations on the requisite testing for KI tablet shelf life extensions, the qualifications of laboratories suitable to conduct the tests, and issues regarding notification of holders of stockpiled KI tablets as well as end users about changes to batch shelf life once testing has been successfully conducted.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**.] General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing

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your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Richard Adams, Center for Drug Evaluation and Research (HFD–643), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5849.

SUPPLEMENTARY INFORMATION:

I. Background

In November 2001, FDA provided guidance on the safe and effective use of KI tablets as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment (66 FR 64046, December 11, 2001). The guidance entitled "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" updated FDA's 1982 recommendations for the use of KI tablets to reduce the risk of thyroid cancer in radiation emergencies involving the release of radioactive iodine. The recommendations in that guidance addressed KI dosage and the projected radiation exposure at which the drug should be used. In April 2002, FDA issued another guidance, "Frequently Asked Questions on Potassium Iodide (KI)." Additional information was provided for emergency pediatric dosing in "Home Preparation Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Small Children," updated on July 3, 2002.

This draft guidance entitled "Potassium Iodide Shelf Life Extension," is intended to provide Federal agencies and State and local governments

information on testing to extend the shelf life of stockpiled potassium iodide (KI) tablets. The agency has developed this document in response to several State inquiries on this topic. This draft guidance discusses FDA recommendations on the requisite testing for such shelf life extensions, the qualifications of laboratories suitable to conduct the tests, and issues regarding notification of holders of stockpiled KI tablets as well as end users about changes to batch shelf life once testing has been successfully conducted.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statues and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 3/25/03
March 25, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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